

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1                   1.       (Currently amended): A computer-implemented method for managing  
2 stability studies, the method comprising:  
3                   storing, in a central database communicatively coupled to a data processing  
4 system, information that defines requirements needed or actions to perform for each stage in a  
5 plurality of stages associated with at least one stability study;  
6                   selecting, with one or more processors associated with the data processing system,  
7 a stage to process from the plurality of stages;  
8                   determining, with one or more processors associated with the data processing  
9 system, one or more requirements needed for the stage of the at least one stability study based on  
10 information retrieved from the central database for the selected stage;  
11                   automatically generating, with the one or more processors associated with the data  
12 processing system, a first graphical user interface based on the one or more determined  
13 requirements needed for the stage, the first graphical user interface configured to display the one  
14 or more determined requirements needed for the stage and accept input from users of the first  
15 graphical user interface for the determined one or more requirements needed for the stage;  
16                   ~~forwarding, to a first client computer, outputting, from the data processing~~  
17 ~~system, information configured to display [[a]] the first graphical user interface on a display~~  
18 ~~device in a first set of one or more graphical user interfaces that enables users of the first client~~  
19 ~~computer to create stability studies by specifying requirements that need to be fulfilled for the~~  
20 ~~stability studies;~~  
21                   ~~receiving, at a first host computer, first input specified by a user of the first client~~  
22 ~~computer via the first interface in the first set of one or more graphical user interfaces, the first~~  
23 ~~input indicative of a set of requirements for at least one stability study;~~

24 determining, with one or more processors associated with the data processing  
25 system, whether one or more actions are to be performed for the stage of the at least one stability  
26 study based on the information retrieved from the central database for the selected stage;

27 automatically generating, with the one or more processors associated with the data  
28 processing system, a second graphical user interface based on one or more determined actions to  
29 be performed for the stage, the second graphical user interface configured to display prompts for  
30 the one or more determined actions to be performed and accept input from users of the second  
31 graphical user interface for the determined one or more actions to be performed;

32 forwarding, to the first client computer, output, from the data processing system,  
33 information configured to display [[a]] the second graphical user interface on a display device in  
34 the first set of one or more graphical user interfaces that enables the users of the first client  
35 computer to create workflows associated with stages of stability studies, a workflow including  
36 information configured to prompt a workflow participant to perform one or more actions that  
37 need to be taken during a stage associated with a stability study in order to fulfill requirements  
38 specified for the stability study;

39 receiving, at the first host computer, input specified by the user of the first client  
40 computer via the second interface in the first set of one or more graphical user interfaces, the  
41 second input indicative of a set of workflows associated with a plurality of stages of the at least  
42 one stability study, each workflow in the set of workflows specifying a set of actions that need to  
43 be taken during each stage in the plurality of stages of the at least one stability study;

44 forwarding, to the first client computer, information configured to display a third  
45 interface in the first set of one or more graphical user interfaces that enable the users of the first  
46 client computer to specify business rules for the stability studies;

47 receiving, at the first host computer, third input specified by the user via the third  
48 interface in the first set of one or more graphical user interfaces, the third input indicative of a set  
49 of business rules for the at least one stability study;

50 generating, at a data processing device, a second set of one or more graphical user  
51 interfaces for the at least one stability study based on the set of requirements that need to be  
52 fulfilled for the at least one stability study, the set of workflows associated with the plurality of

53 ~~stages of the at least one stability study, and the set of business rules for the at least one stability~~  
54 ~~study, wherein the second set of one or more graphical user interfaces define the set of~~  
55 ~~requirements for the at least one stability study;~~  
56 ~~forwarding, to a second client computer, information configured to display one or~~  
57 ~~more interfaces in the second set of graphical user interfaces;~~  
58 ~~receiving, at the data processing system second host computer, information~~  
59 ~~specified by one or more users of the second client computer via the one or more first or second~~  
60 ~~graphical user interfaces in the second set of interfaces, the received information for fulfilling~~  
61 ~~satisfying at least one of the one or more determined requirements or resulting from performance~~  
62 ~~to the one or more actions of the at least one stability study; and~~  
63 ~~validating, with the one or more processors associated with the data processing~~  
64 ~~system by the second host computer, the received information against [[the]] a set of business~~  
65 ~~rules for the at least one stability study to determine whether the received information is~~  
66 ~~acceptable.~~

1 2. (Previously presented): The method of claim 1, further comprising if the  
2 information specified by the one or more users of the second client computer is acceptable,  
3 storing the information specified by the one or more users of the second client computer using a  
4 storage device.

1 3. (Previously presented): The method of claim 1, further comprising:  
2 determining, by the data processing device, whether the set of requirements for  
3 the at least one stability study have been completed; and  
4 if the set of requirements have not been completed, requesting, using the data  
5 processing device, additional information for the requirements in the set of requirements that  
6 have not been completed.

1 4. (Previously presented): The method of claim 1, further comprising:  
2 determining, by the data processing device, whether approval from a user is  
3 needed for the information specified by the one or more users of the second client computer

4 based on the set of workflows associated with the plurality of stages of the at least one stability  
5 study.

1           5.       (Previously presented): The method of claim 4, further comprising:  
2           receiving, at the data processing device, an indication of approval for the  
3 information specified by the one or more users of the second client computer; and  
4           storing the indication using a storage device.

1           6.       (Original): The method of claim 5, wherein the indication comprises at  
2 least one of an electronic signature and captured signature.

1           7.       (Previously presented): The method of claim 4, further comprising:  
2           receiving, at the data processing device, an indication of disapproval for the  
3 information specified by the one or more users of the second client computer;  
4           determining, by the data processing device, requirements that need to be  
5 completed for approval; and  
6           requesting, using the data processing device, that the determined requirements be  
7 completed for approval.

1           8.       (Previously presented): The method of claim 1, wherein the first set of  
2 one or more graphical user interfaces include an interface for a stage in the plurality of stages in  
3 the at least one stability study.

1           9.       (Original): The method of claim 8, wherein the plurality of stages  
2 comprise at least two of a stability study setup criteria, stability study planning criteria, initial  
3 sampling and testing criteria, stability study launch criteria, stability study testing criteria, and  
4 stability study evaluation criteria.

1           10.      (Currently amended): The method of claim 1, further comprising  
2 outputting, from the data processing device, information summarizing the at least one stability  
3 study.

1                   11.     (Previously presented): The method of claim 1, further comprising  
2     determining, by the data processing device, a result of the at least one stability study.

1                   12.     (Previously presented): The method of claim 11, wherein determining, by  
2     the data processing device, the result of the at least one stability study comprises receiving the  
3     result from a user.

13-26 (Canceled).

1                   27.     (Previously presented): A tangible computer readable medium storing a  
2     set of instructions for managing a stability study when executed by a processor of a data  
3     processing system, the computer readable medium comprising:  
4                   code for forwarding information configured to display a first interface in a first set  
5     of one or more graphical user interfaces that enable a user to create stability studies by specifying  
6     requirements that need to be fulfilled for the stability studies;  
7                   code for receiving first input via the first interface in the first set of one or more  
8     graphical user interfaces, the first input indicative of a set of requirements for at least one  
9     stability study;  
10                  code for forwarding information configured to display a second interface in the  
11     first set of one or more graphical user interfaces that enable a user to create workflows associated  
12     with stages of stability studies, a workflow including information configure to prompt a  
13     workflow participant to perform one or more actions that need to be taken during a stage  
14     associated with a stability study in order to fulfill requirements specified for the stability study;  
15                  code for receiving second input via the second interface in the first set of one or  
16     more graphical user interfaces, the second input indicative of a set of workflows associated with  
17     a plurality of stages of the at least one stability study, each workflow in the set of workflows  
18     specifying a set of actions that need to be taken during for each stage in the plurality of stages of  
19     the at least one stability study;

code for forwarding information configured to display a third interface in the first set of one or more graphical user interfaces that enable a user to specify a set of business rules for stability studies;

code for receiving third input via the third interface in the first set of one or more graphical user interfaces, the third input indicative of a set of business rules for the at least one stability study;

code for generating a second set of one or more graphical user interfaces for the at least one stability study based on the set of requirements that need to be fulfilled for the at least one stability study, the set of workflows associated with the plurality of stages of the at least one stability study, and the set of business rules for the at least one stability study, wherein the second set of one or more fourth interfaces define the set of requirements for the at least one stability study;

code for forwarding information configured to display one or more interfaces in the second set of graphical user interfaces;

code for receiving fourth input via the one or more interfaces in the second set of graphical user interfaces, the received fourth input for fulfilling the requirements of the at least one stability study; and

code for validating the received fourth input against the set of business rules for the at least one stability study to determine whether the fourth input is acceptable.

28. (Previously presented): The computer readable medium of claim 27, further comprising code for storing the fourth input when the fourth input is acceptable.

29. (Previously presented): The computer readable medium of claim 27, further comprising:

code for determining whether the set of requirements for the at least one stability study have been completed; and

code for requesting additional information for the requirements in the set of requirements that have not been completed.

1                   30.     (Previously presented): The computer readable medium of claim 27,  
2 further comprising:  
3                   code for determining whether approval from a user is needed for the fourth input  
4 based on the set of workflows associated with the plurality of stages of the at least one stability  
5 study.

1                   31.     (Previously presented): The computer readable medium of claim 30,  
2 further comprising:  
3                   code for receiving an indication of approval for the fourth input; and  
4                   code for storing the indication.

1                   32.     (Previously presented): The computer readable medium of claim 31,  
2 wherein the indication comprises at least one of an electronic signature and captured signature.

1                   33.     (Previously presented): The computer readable medium of claim 30,  
2 further comprising:  
3                   code for receiving an indication of disapproval for the fourth input;  
4                   code for determining requirements that need to be completed for approval; and  
5                   code for requesting that the determined requirements be completed for approval.

1                   34.     (Previously presented): A system for managing stability studies, the  
2 system comprising:  
3                   a set of one or more processors; and  
4                   one or more memories coupled to the set of processor, the one or more memories  
5 including:  
6                   a first set of one or more graphical user interfaces configured to enable a  
7 user to create stability studies by specifying requirements that need to be fulfilled for stability  
8 studies, workflows associated with stages of stability studies, and business rules for stability  
9 studies;

10 a database configured to store information associated with the  
11 requirements, the workflows, and the business rules for stability studies, wherein a workflow  
12 includes information configured to prompt a user to perform one or more actions that need to be  
13 taken during a stage associated with a stability study in order to fulfill requirements specified for  
14 the stability study;

15 a stage selector configured to select a stage of a stability study;  
16 a stage information manager configured to receive from the database one  
17 or more requirements that need to be fulfilled for the selected stage and one or more workflows  
18 associated with the selected stage, to generate a second set of one or more graphical user  
19 interfaces that defines the one or more requirements for the selected stage that need to be  
20 fulfilled and actions associated with the selected stage that need to be performed;

21 a stage information processor configured to receive input specified via the  
22 second set of graphical user interfaces and to validate the input against business rules associated  
23 with the selected stage to determine whether the input is acceptable.

1 35. (Previously presented): The system of claim 34 wherein the first set of  
2 one or more graphical user interfaces is further configured to enable the user to create a  
3 specification for a first stability study as an overlay using a specification for a second stability  
4 study as a base.